EXECUTIVE SUMMARY

LEARNING WHAT WORKS BEST

THE NATION'S NEED FOR EVIDENCE ON COMPARATIVE EFFECTIVENESS IN HEALTH CARE

IOM ROUNDTABLE ON EVIDENCE-BASED MEDICINE

– An Issue Overview –

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

ACKNOWLEDGEMENTS

This Issue Overview on current and needed capacity for comparative effectiveness research was developed by staff of the IOM Roundtable on Evidence-Based Medicine as background material for the activities of the Roundtable's Sustainable Capacity Working Group, and to inform discussion at the March 19, 2007 Roundtable meeting.

Guidance on structure and content were provided by members of an advisory group including: Carmella Bocchino (AHIP), Queta Bond (Burroughs Wellcome Fund), Kathy Buto (Johnson & Johnson), Steve Galson (FDA), Mark McClellan (AEI-Brookings Joint Center for Regulatory Studies), Lisa Payne-Simon (Blue Shield of California Foundation), Diana Petitti (University of Southern California), Jean Slutsky (AHRQ), Sean Tunis (Center for Medical Technology Policy), and Gail Wilensky (Project Hope).

We also extend special thanks to those who took the time to review and comment on various sections or draft versions of this paper including: Wade Aubry (HealthTech), Tanisha Carino (Avalere Health), Mark Gibson (DERP), Carmen Hooker Odom (North Carolina HHS), Michael Johns (Emory), Peter Juhn (Johnson & Johnson), Doug Owens (Stanford), Steve Pearson (AHIP), Steve Phurrough (CMS), Eugene Rich (Senate Health Subcommittee, Committee on Ways and Means), Wayne Rosenkrans, Jr. (AstraZeneca), and Jeff Shuren (FDA).

IOM staff and fellows who contributed include: Dara Aisner, Katharine Bothner, Pamela Bradley, Michael McGinnis, LeighAnne Olsen, and Dan O'Neill.

Roundtable sponsors: The work of the Roundtable is supported by the Agency for Healthcare Research and Quality, AHIP (America's Health Insurance Plans), AstraZeneca, Blue Shield of California Foundation, Burroughs Wellcome Fund, California Healthcare Foundation, Centers for Medicare and Medicaid Services, Department of Veterans Affairs, Food and Drug Administration, the HWG Fund, Johnson & Johnson, sanofi-aventis, and Stryker.

Suggested citation: Institute of Medicine. 2007. *Learning What Works Best: The Nations Need for Evidence on Comparative Effectiveness in Health Care*. http://www.iom.edu/ebm-effectiveness.

IOM ROUNDTABLE ON EVIDENCE-BASED MEDICINE

Working Group on Sustainable Capacity*

LEARNING WHAT WORKS BEST

THE NATION'S NEED FOR EVIDENCE ON COMPARATIVE EFFECTIVENESS IN HEALTH CARE

Executive Summary

A core objective for the nation is achieving the best health outcome for every patient. This objective simply cannot be accomplished until we have better evidence on which to base healthcare decisions, as well as more effective application of the knowledge we have. Each is vitally important. This paper provides background for discussion about the evidence gap—the fact that the nation's capacity has fallen far short of the need to produce reliable and practical information about the care that works best. Medical care decision-making is now strained, at both the level of the individual patient and the level of the population as a whole, by the growing number of diagnostic and therapeutic options for which evidence is insufficient to make a clear choice. Consequences are seen in broad geographic variation in the intensity of services delivered for the same outcome; in the occurrence of medical errors; in patient and provider confusion about which interventions deliver the most value; and in the costs of care.

Testament to innovation is the fact that new pharmaceuticals, medical devices, biologics and procedures are introduced constantly, and the pace is quickening. From 1991 to 2003, the number of medical device patents per year doubled, and biotechnology patents tripled. Between 1993 and 2004, there was an 80% increase in the number of prescriptions received by Americans. A recent review suggests that half or more of the growth in medical spending in recent years is attributable to change in technology.

In addition to the growth in application of drugs, devices, biologics, and procedures, the world of health care is about to experience dramatic new insights on the genetic variation in individual response to different diagnostic and treatment interventions. The age of personalized medicine will soon be a reality, if the capacity can be developed to contend with its insights. Today, the average clinical encounter already requires a health provider to manage more variables than would be considered reasonable given what is known about the capabilities of the human mind, and over the next decade that same encounter will require contending with perhaps an order of magnitude additional complexity.

These developments hold fundamental implications for health prospects, and, to capture and use them effectively and efficiently, a proportionate commitment is required to understand their advantages and appropriate applications. Yet, of the nation's more than $2 trillion annual health expenditure—now 20% higher than any other country in the world—less than 0.1% is invested in assessing the comparative effectiveness of available interventions. Of this, the $15 million specifically appropriated by Congress for comparative effectiveness research is just a small fraction.

---

* Jack Rowe/Columbia University (Chair), Adam Bosworth/Google, Helen Darling/National Business Group on Health, Michael Johns/Emory University, Steve MacMillan/Stryker Corporation, Mark McClellan/AEI-Brookings, Richard Platt/Harvard University, Steve Udvarhelyi/Independence Blue Cross, Bill Weldon/Johnson & Johnson, Janet Woodcock/FDA. The material here is a staff paper prepared at the request of the Working Group. Information on the IOM Roundtable on Evidence-Based Medicine may be obtained at www.iom.edu/ebm.

If only 1% of the nation's healthcare bill were devoted to understanding the effectiveness of the care purchased, the total would come approximately to $20 billion annually. In contrast, even accounting for the support from all private and public sources, the aggregate national commitment to assessing the effectiveness of clinical interventions is still likely well under 1%—far below the standard that any company would expect to invest in work to evaluate and improve its products.

Regardless of individual perspectives on reform of the many challenging issues in health policy today, there is little question about the critical need for better information for patients and providers to make their decisions about the comparative advantages of healthcare options. This paper provides background context and summarizes issues and options for discussions of how to proceed on this matter of central importance to health and health care. It does not provide recommendations.

Implications for stakeholders

For patients, the stakes are very clear. Every patient should be able to feel confident that there is solid evidence to support the notion that the care received is the care most appropriate to the circumstances. Yet, increasingly this notion is strained. In a 2005 survey, 60% of Americans said they didn't believe that the U.S. had the best health care system in the world, 41% said they knew of a time when they or a family member had received the wrong care, and 56% said there should be more investment in clinical and health services research. Health providers feel similar tensions. No health professional should be put in the position of uncertainty about the evidence in support of the care provided at their behest. Yet, with the pace of advances in medical procedures, pharmaceuticals, devices, and biotechnology, a sometimes confusing array of choices is presented for patients, their healthcare providers, and the healthcare organizations in which care is delivered. The integrity and reputation of healthcare delivery organizations is dependent on their ability to ensure the quality and appropriateness of the care delivered within their walls. Any decision support system is only as good as the information built into the model and should include the comparative advantages or disadvantages of different diagnostic and therapeutic options.

Healthcare manufacturers, focused as they are on returns on investment, inherently understand the importance of improving the value proposition in patient care. But their stakes go deeper. Manufacturers directly bear the economic burden of delays and inefficiencies when information is not available about the advantage of their products, not to mention the challenges of public and shareholder backlash when problems are identified too late. Without a sizable improvement in our evaluative capacity, the slower pace of understanding how and when interventions work best will retard the application of potential innovations.

From a purchasing perspective, the need for better information is of central importance to those who pay for healthcare: patients, employers, insurers, and the government. Over half of the nation's health expenditures are borne by the private sector, including a sizable share by employers. For the fourth consecutive year, chief executive officers of U.S. companies have cited health care costs as their number one economic concern. Employers now pay 78% more for health care than five years ago, and it has been suggested by some that this increased financial burden make it more difficult for American companies and workers to compete in the global marketplace. Often acting on behalf of employers, insurers represent the front line of the economic choices that have to be made on payment for healthcare services. This means drawing conclusions about comparative advantages or disadvantages of proposed diagnostic or treatment interventions, in the face of a paucity of such information, especially information applicable to "real world" circumstances. As a payer, government accounts for about 45% of health expenditures in the United States, including care it

delivers directly in its own facilities. Whether as a payer or a provider, government has a central interest in ensuring that its clients receive the care that is most appropriate and of the greatest value.

Current activities in clinical effectiveness research

Currently, activities to assess the effectiveness of health care interventions are broad but under-resourced and fall far short of the need. Clinical effectiveness research can be described as either primary or secondary. Primary refers to the direct generation of evidence through the use of a specific experimental methodology. Secondary refers to the evidence synthesis from multiple primary studies to draw conclusions for practice. Within the overall umbrella of clinical effectiveness research, the most practical need is for studies of comparative effectiveness, the comparison of one diagnostic or treatment option to one or more others.

The largest investment in clinical effectiveness research is made by industry, with industry-sponsored clinical trials representing a significant proportion of health manufacturer investments in research and development. For example, about 40% of pharmaceutical R&D investments goes to the phase 3 and 4 trials that have particular relevance to clinical effectiveness. Many of these studies are conducted with academic investigators and others are managed by contract research organizations. Relatively few of the studies are comparative, or head-to-head studies.

Outside industry, several government agencies support clinical effectiveness research, including the Agency for Healthcare Research and Quality (AHRQ), which has a specific mandate and the small appropriation noted earlier for comparative effectiveness research. The total of all appropriations to all federal agencies—the National Institutes of Health (NIH), the Veteran's Health Administration (VHA), the Department of Defense (DOD), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), AHRQ, and the Centers for Disease Control and Prevention (CDC)—for all health services research amounts to about $1.5 billion, only a modest portion of which is devoted to clinical effectiveness research—far below the industry level. Additional work, also modest, is undertaken by certain of the larger healthcare delivery organizations. Evidence synthesis activity is supported by the insurance industry, professional societies, healthcare organizations, and government. AHRQ has established a network of 13 AHRQ-sponsored Evidence-based Practice Centers that review literature and produce evidence reports including Comparative Effectiveness Reviews. Organizations interested in evidence reviews will often draw upon syntheses performed by several well-established technology assessment entities.

Activities and needs related to comparative effectiveness research

Table 1

Prominent CER Activities and Needs
1. Studies of comparative effectiveness ("head to head")
2. Systematic reviews of comparative effectiveness
3. Assessment of comparative value/cost effectiveness
4. Coordinated priority setting and execution
5. Improved study designs and research methods
6. Better linkage of studies of efficacy, safety, and effectiveness
7. Appropriate evidence standards consistently applied
8. Consistent recommendations for clinical practice
9. Guidance for coverage and funding
10. Dissemination, application, and public communication

As broad and variegated is the interest and activity around clinical effectiveness, the aggregate capacity is very thin, and the products fall substantially short of the need. Because of the scant resources for support of primary comparative effectiveness research—head-to-head studies—much of the work is, of necessity, secondary evidence synthesis. Yet the most pressing needs of clinicians and their patients are for reliable studies on which to base their decisions. The elements of the needs have been characterized in various ways, and can be grouped into the key areas indicated in Table 1. Below is a summary of the key challenges that must be engaged in each of these areas.

Table 2

Issue	Key challenges
Head-to-head studies	scant resources; rapidly increasing need; comparison choice
Systematic reviews	few primary studies; inconsistent methods; uncoordinated
Comparative value insights	little agreement on metrics or role of costs; cost fluctuation
Priority setting	fragmentation; inefficiency; no mechanism for coordination
Study designs and tools	clinical trial time/cost/limits; large data set mining methods
Research lifecycle links	efficacy-effectiveness disjuncture; post-approval surveillance
Evidence standards	standards unadapted to needs; inconsistency in application
Practice guidance	Disparate approaches; conflicting recommendations
Coverage guidance	narrow evidence base; limited means for provisional coverage
Application tools	public misperceptions; incentive structures; decision support

Models for a stronger approach to comparative effectiveness research

To narrow the rapidly growing gap between the available evidence on clinical effectiveness and the evidence necessary for sound clinical decision-making, various organizations and recent public articles have called for the creation of a new entity and a quantum increase—several billion dollars—for comparative effectiveness research. The several approaches to building the required capacity can be grouped into four categories according to the funding patterns for their support (Table 3). Each of the approaches is based on an existing or recent model of some kind. Although presented as discrete models for discussion purposes, they are not mutually exclusive.

Table 3

Models for Enhancing Capacity
Incremental funding augmentations
§ Incremental model
Public funded entity
§ Executive branch agency model
§ Independent government commission model
§ Legislative branch office model
Private funded entity
§ Operating foundation model
§ Investment tax credit cooperative model
Public-private funded entity
§ User fee public model
§ FFRDC public model
§ Independent cooperative model
§ Independent quasi-governmental authority model

The most straightforward public funded approach is an expanded and appropriated mandate to an existing or newly created federal agency, and the agency whose mandate most closely parallels these priorities is AHRQ. Through its Effective Health Care program, AHRQ has an existing framework for many elements of the identified needs. Other Executive Branch models include location of the primary capacity in NIH, elsewhere in the Department of Health and Human Services, or as a free-standing operational Federal agency.

Other possibilities include approaches that are solely private funded, although this raises issues of independence and objectivity, and those that represent a blend of public and private funding, with different governing and execution structures. In the latter category are those based on the quasi-governmental Federally-Funded Research and Development Centers (FFRDCs)—which are funded primarily by the federal government, but allowed up to 30% funding from private sources, and are private entities managed by non-governmental organizations—and those based on the examples of free-standing independent quasi-governmental entities such as the Federal Reserve Board that serves as the nation's central banking system, and the National Academy of Science's Institute of Medicine and the Transportation Research Board (TRB). TRB, from its National Academies locus, houses publicly and privately-funded work in transportation that is conceptually similar in structure to what is envisioned for comparative effectiveness.

Decision and implementation considerations

Weighing the relative strengths and weaknesses of the various models can begin with certain touchstone principles that have been suggested to help guide their consideration. These include the characteristics of the approaches with respect to:

- *Scientific credibility:* ability to gain the trust and confidence of the public, the scientific community, and the other stakeholders involved.
- *Political independence:* well-insulated from the political processes that interests from all perspectives will seek to leverage.
- *Stakeholder neutrality:* ability to engage with all stakeholders—patients, providers, employers, manufacturers, and insurers—in an independent, even-handed fashion.
- *Participatory governance:* affording the opportunity for relevant stakeholders to engage as appropriate in priority-setting and agenda-setting, while safeguarding the scientific integrity.
- *Investigator integrity:* management and conduct of the research processes, and the determination and validation of research results completely insulated from outside influence.
- *Agenda flexibility:* organizational decision-making, resource allocation, and program conduct with the flexibility to respond quickly to emerging issues and changing circumstances.
- *Infrastructure efficiency:* use where possible existing capacity for the establishment of scientific standards and for the management and conduct of studies.

- *Transparency of processes and results:* specification and availability of the data on which determinations are based, and clarity as to the processes and tools used in their evaluation.

Other implementation considerations include those related to funding and program management. As noted earlier, funding estimates are in the range of several billion dollars. This is a sizable amount, although not in the context of the $2 trillion spent on healthcare, and not in the context of the efficiencies that could be gained. Suggestions for the mechanism range from direct annual federal appropriation, to a small set-aside from the Medicare Trust Fund, to the structuring of proportionately matching contributions including set-asides from Medicare fund expenditures, from private health insurance premiums, and/or manufacturer R&D expenditures. There can be many variations on these themes, but the key concept is less related to the source of the funds invested than to the value of the return for the outcomes and efficiency of the nation's health care.

Independent approaches most commonly discussed

Because of the challenges to increasing comparative effectiveness research primarily through a simple appropriation to an existing agency—difficulty of marshaling an appropriation at a sufficient level, lack of political independence, limited ability to draw on other agencies—much of the recent discussion has focused on three of the independent models, often with blended public and private funding. Table 4 presents these as the Agency-Linked, Independent Board, and Hybrid models.

Table 4

Comparative Effectiveness Research Enterprise Models			
Activity	**Agency-Linked**	**Independent Board**	**Hybrid**
Reference model	FFRDC entity	Federal Reserve Board	FRB/TRB/NAS
Priority setting	Governing Board	Governing Board	Governing Board
Budget allocation	Governing Board	Governing Board	Governing Board
Study selection	FFRDC entity	Board staff/panel	IOM NAS
Design/methods	FFRDC entity	Agencies/IOM	IOM NAS
Agency designation	FFRDC entity	Governing Board	IOM NAS
Study management	AHRQ/entity	TBD	Existing federal agencies
Study conduct*	Entity/agencies/field	Agencies/field	Agencies/Field
Study certification	FFRDC entity	Governing Board	IOM NAS
Study conclusions	FFRDC entity	Governing Board	IOM NAS
Dissemination	TBD	Field	IOM NAS
Advantages	AHRQ-associated	independent	independent
			established credibility
			governance/sci firewall
			use all agencies
Disadvantages	Politically vulnerable	need to build credibility	GB/NAS rel'n-dependent
	linked to one agency	duplicates capacity	

*Conduct assigned by study type—primary (e.g. trials) or secondary (e.g. syntheses) research.

As independent entities, each of these approaches assumes the establishment of a Governing Board comprised of stakeholders and charged with priority setting, broad budget allocation, and fiduciary responsibility for execution of the program of activities. They differ in the degree of insulation

between the stakeholder priority setting and the conduct of the scientific studies, as well as in the ways those studies would be managed, involvement of existing agencies, and reporting of results.

Concluding observations

As ever-increasing options evolve in health care, current gaps in knowledge and practice about which care works best will persist or worsen without the appropriate information on which to base healthcare decisions. The rate with which new interventions are introduced into the medical marketplace is currently outpacing the rate at which information is generated on their effectiveness and the circumstances of best use. If trends continue, the ability to deliver appropriate care will be strained and may be overwhelmed. A substantially increased capacity to conduct and evaluate research on clinical effectiveness of interventions brings many potential opportunities for improvement across a wide spectrum of healthcare needs. In time, the enhanced capacity to identify and apply the most appropriate care will both improve health and support innovation, by identifying the areas where it is needed most. The options reviewed here offer a sense of the possibilities and opportunities, but the need for swift action is pressing.

Appendices

1. Current National Capacity for Clinical Effectiveness Research
2. International Activities in Clinical Effectiveness Research
3. Potential model: Federally Funded Research and Development Centers
4. Potential model: NIH Public-Private Partnership Program
5. Potential model: National Academies' Transportation Research Board
6. Potential model: Federal Reserve Board
7. Commissioned analysis: The Business Case for Comparative Effectiveness Research

The full text of the report and the appendices can be obtained at http://www.iom.edu/ebm-effectiveness.

INSTITUTE OF MEDICINE ROUNDTABLE ON EVIDENCE-BASED MEDICINE

Charter and Vision Statement

The Institute of Medicine's Roundtable on Evidence-Based Medicine has been convened to help transform the way evidence on clinical effectiveness is generated and used to improve health and health care. We seek the development of a ***learning health care system*** that is designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care.

Vision: Our vision is for a health care system that draws on the best evidence to provide the care most appropriate to each patient, emphasizes prevention and health promotion, delivers the most value, adds to learning throughout the delivery of care, and leads to improvements in the nation's health.

Goal: By the year 2020, ninety percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence. We feel that this presents a tangible focus for progress toward our vision, that Americans ought to expect at least this level of performance, that it should be feasible with existing resources and emerging tools, and that measures can be developed to track and stimulate progress.

Context: As unprecedented developments in the diagnosis, treatment, and long-term management of disease bring Americans closer than ever to the promise of personalized health care, we are faced with similarly unprecedented challenges to identify and deliver the care most appropriate for individual needs and conditions. Care that is important is often not delivered. Care that is delivered is often not important. In part, this is due to our failure to apply the evidence we have about the medical care that is most effective—a failure related to shortfalls in provider knowledge and accountability, inadequate care coordination and support, lack of insurance, poorly aligned payment incentives, and misplaced patient expectations. Increasingly, it is also a result of our limited capacity for timely generation of evidence on the relative effectiveness, efficiency, and safety of available and emerging interventions. Improving the value of the return on our health care investment is a vital imperative that will require much greater capacity to evaluate high priority clinical interventions, stronger links between clinical research and practice, and reorientation of the incentives to apply new insights. We must quicken our efforts to position evidence development and application as natural outgrowths of clinical care—to foster health care that learns.

Approach: The IOM Roundtable on Evidence-Based Medicine serves as a forum to facilitate the collaborative assessment and action around issues central to achieving the vision and goal stated. The challenges are myriad and include issues that must be addressed to improve evidence development, evidence application, and the capacity to advance progress on both dimensions. To address these challenges, as leaders in their fields, Roundtable members will work with their colleagues to identify the issues not being adequately addressed, the nature of the barriers and possible solutions, and the priorities for action, and will marshal the resources of the sectors represented on the Roundtable to work for sustained public-private cooperation for change. Activities include collaborative exploration of new and expedited approaches to assessing the effectiveness of diagnostic and treatment interventions, better use of the patient care experience to generate evidence on effectiveness, identification of assessment priorities, and communication strategies to enhance provider and patient understanding and support for interventions proven to work best and deliver value in health care.

Core concepts and principles: For the purpose of the Roundtable activities, we define evidence-based medicine broadly to mean that, *to the greatest extent possible, the decisions that shape the health and health care of Americans—by patients, providers, payers and policymakers alike—will be grounded on a reliable evidence base, will account appropriately for individual variation in patient needs, and will support the generation of new insights on clinical effectiveness.* Evidence is generally considered to be information from clinical experience that has met some established test of validity, and the appropriate standard is determined according to the requirements of the intervention and clinical circumstance. Processes that involve the development and use of evidence should be accessible and transparent to all stakeholders.

A common commitment to certain principles and priorities guides the activities of the Roundtable and its members, including the commitment to: the right health care for each person; putting the best evidence into practice; establishing the effectiveness, efficiency and safety of medical care delivered; building constant measurement into our health care investments; the establishment of health care data as a public good; shared responsibility distributed equitably across stakeholders, both public and private; collaborative stakeholder involvement in priority setting; transparency in the execution of activities and reporting of results; and subjugation of individual political or stakeholder perspectives in favor of the common good.

IOM ROUNDTABLE ON EVIDENCE-BASED MEDICINE

Roundtable Chair:

Denis A. Cortese, M.D.
President and CEO
Mayo Clinic

Roundtable Members:

Adam Bosworth
Vice President of Engineering
Google Inc.

David R. Brennan
CEO
AstraZeneca PLC

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Helen Darling
President
National Business Group on Health

James A. Guest
President
Consumers Union

George C. Halvorson
Chairman and CEO
Kaiser Permanente

Carmen Hooker Odom
Secretary
Health & Human Services
State of North Carolina

Michael M.E. Johns, M.D.
Executive Vice President
Emory University
CEO, Health Sciences Center
Chairman of the Board
Emory Health Care

Michael J. Kussman, M.D., M.S., M.A.C.P
Under Secretary for Health
Department of Veterans Affairs

Cato T. Laurencin, M.D., Ph.D.
Lillian T. Pratt Distinguished Professor
Chairman of Orthopedic Surgery
University of Virginia

Stephen P. MacMillan
President and CEO
Stryker

Mark B. McClellan, M.D., Ph.D.
Senior Fellow
AEI-Brookings Joint Center for Regulatory Studies

Elizabeth G. Nabel, M.D.
Director
National Heart, Lung and Blood Institute

Peter M. Neupert, M.B.A.
Corporate Vice President
Health Solutions Group
Microsoft

Nancy H. Nielsen, M.D., Ph.D.
Speaker of the House of Delegates
American Medical Association

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services

Jonathan B. Perlin, M.D., Ph.D., M.S.H.A., F.A.C.P.
Senior Vice President for Quality and Chief Medical Officer
HCA, Inc.

Richard Platt, M.D., M.S.
Professor and Chair
Harvard Medical School
Harvard Pilgrim Health Care

John C. Rother, J.D., M.A.
Group Executive Officer
Policy and Strategy
AARP

Tim Rothwell, J.D., M.B.A.
Chairman
sanofi-aventis U.S.

John W. Rowe, M.D.
Former Chairman and CEO
Aetna, Inc.
Professor
Columbia University

Donald M. Steinwachs, Ph.D.
Professor
Bloomberg School of Public Health
Johns Hopkins University

Andrew L. Stern
President
Service Employees International Union

I. Steven Udvarhelyi, M.D., S.M.
Senior Vice President and Chief Medical Officer
Independence Blue Cross

Frances M. Visco
President
National Breast Cancer Coalition

William C. Weldon
Chairman and CEO
Johnson & Johnson

Janet Woodcock, M.D.
Deputy Commissioner
and Chief Medical Officer
Food and Drug Administration